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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/010,244

12/06/2001

Robert Sixto JR.

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EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

05/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/010,244	Applicant(s) SIXTO ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-35 is/are pending in the application.
- 4a) Of the above claim(s) 13-25 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27,28,31,32,34 and 35 is/are allowed.
- 6) ☒ Claim(s) 1,7-12,26,29,30 and 33 is/are rejected.
- 7) ☒ Claim(s) 2-5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/5/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The applicant's amendment filed on 1/9/08 has been entered into the application.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 10/15/07 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 12 recites that the tissue comprises two separate pieces of tissue, which contradicts the limitation of independent claim 1, which states that the body tissue is a folded tissue. Since a "folded tissue" cannot be "separate pieces of tissue", the claim is rendered vague and indefinite.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3773

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 7-12, 26, 29, 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,434,796 to Karapetian et al. in view of US 5,403,326 to Harrison et al.

As to claims 1, 11, 12, 26, 29 and 33, Karapetian discloses a method of advancing a clip having two substantially parallel legs **1**, each having a pointed piercing end and a bridge portion coupling the two arms, such that a body tissue is located

between the two arms (Fig. 1); and subsequently bending both piercing portions through more than one half the thickness of the body tissue while the arms remain substantially parallel to each other (Fig. 2); wherein the clip is advanced with a single instrument (Fig. 5); wherein said tissue are two separate pieces of tissue having their own thicknesses; wherein only said piercing portion is bent. It is noted that the applicant has not clearly stated which portion of the tissue defines the “thickness”. Therefore, the examiner is viewing the thickness of the portion of the tissue that corresponds to the width of the staple (not the length).

Karapetian discloses all the steps of the claimed medical method except for the step of manipulating the tissue to form a fold (two layers from the same tissue). Instead, Karapetian discloses two layers formed from separate tissues.

However, the use of a clip to attach folded tissue is well known in the art. For instance, Harrison discloses a method of attaching folded tissue together using a clip and anchor (Fig. 8C), which is similar to the clip disclosed by Karapetian.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methodology of Karapetian to include the step of attaching folded tissue together since it is known in the art to use clips to attach folded tissues together, as taught by Harrison, and that it has been held that use of a known technique (attaching folded tissues with clips) to improve similar devices (clip applier) will provide predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

As to claims 7-10 and 30, Harrison discloses that the body tissue could be the fundus., wherein the tissue is manipulated by a grasper **72** to compress the tissues together (Fig. 8C); wherein the method is performed by a single instrument. Therefore, one of ordinary skill in the art would have found it obvious to modify the methodology and device of Karapetian to include the steps and structures of the device of Harrison because it would allow a practitioner to manipulate a folded tissue and provide a clip to the folded tissue with a single instrument.

Allowable Subject Matter

11. Claims 2-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Claims 27, 28, 31, 32, 34 and 35 are allowed.

Response to Arguments

13. The indicated allowability of claims 6-10, 29 and 30 is withdrawn in view of the newly discovered reference(s) to Harrison et al., as applied above. The applicant has amended the independent claims to incorporate the subject matter of claim 6. Thus, the applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezzo/
Primary Examiner, Art Unit 3773